Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Protocol summary

Study aim
Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Design
This randomized clinical trial was conducted to evaluate effect of vitamin E in prevention of hyper billirubinemia in preterm newborn with gestational age between 34 to 37 weeks born in Alzahra and Shahidbeheshti Hospital affiliated to Isfahan University of Medical Sciences. written informed consent was taken from the child's parents. The infants were randomly allocated to either the case or the control group by a simple randomization method using a table of random numbers. One hundred neonates with gestational age between 34 to 37 weeks were enrolled in this study. The neonates were randomly divided in two groups matched for age and gender. Immediately after birth For the cases group (consist of 50 newborn) 10 units of vitamin E (1 cc of vitamin E per a drop) and in the control group (consist of 50 newborn) 1 cc distilled water was administered orally for five days. In the 0,24,48,72 and 96 Hour of life, Transcutaneous Billirubinometery was conducted to evaluate level of bilirubin in neonates of two groups. The results was analyzed via t-test and x2-test. P value less than 0/05 was considered significant.

Settings and conduct
Alzahra and Shahid beheshti Hospitals in Isfahan

Participants/Inclusion and exclusion criteria
Preterm newborns with GA between 34 to 37 weeks Exclusive breast feeding Apgar score> 7 in fifth minute lack of neonatal sepsis lack of abdominal distentions or lavage lack of history of exchange transfusion in previous sibling

Intervention groups
For the cases group (consist of 50 newborn) 10 units of vitamin E (1 cc of vitamin E per a drop) and in the control group (consist of 50 newborn) 1 cc distilled water was prescribed orally for five days

Main outcome variables
Neonatal Jaundice

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150423021910N4**
Registration date: **2019-01-04, 1397/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-04, 1397/10/14**
Update count: **0**

Registration date
2019-01-04, 1397/10/14

Registrant information

Name
Behzad Barekatain

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3261 6670

Email address
b_barekatain@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-07-23, 1396/05/01

Expected recruitment end date
2019-02-19, 1397/11/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of vitamin E in serum bilirubin level in preterm neonates with gestational age between 34 and 37 weeks

Public title

Effect of Vit E on billirubin level in preterm newborns

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

preterm newborns with GA between 34 to 37 weeks Exclusive breast feeding Apgar score > 7 at fifth minute of life

Exclusion criteria:

lack of abdominal distention or lavage lack of history of exchange transfusion in previous siblings lack of neonatal sepsis

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **5**

Measurement of billirubin via Transcutaneous Billirubinometer

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random number was used. We use 100 tumultuous numerical table and we selected columns in the form of decussate and assigned its numbers to each groups (intervention and control groups)

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study the student and neonatal unit staffs dont know which types of drugs (Vit E or placebo) is prescribed. Transcutaneous Billirubinometery was performed by student that did not know which type of drugs prescribed by physician.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjerib boulevard, Isfahan University of Medical Scienses

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2017-05-07, 1396/02/17

Ethics committee reference number

IR.MUI.REC.1396.3.071

Health conditions studied

1

Description of health condition studied

Neonatal Jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Neonatal Jaundice

Timepoint

In 0 , 24 , 48 , 72 , 96 Hours

Method of measurement

Transcutaneous Billirubinometer

Secondary outcomes

1

Description

Sepsis

Timepoint

During Study

Method of measurement

Clinical Sign and Blood Culture

Intervention groups

1

Description

Intervention group: In Intervention group we prescribed

10 unit of Vit E (equall to 1 cc) orally once in day for 5 days

Category

Prevention

2

Description

Control group: In control group we prescribed 1 cc of distilled water orally once in day for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Behzad Barekatain

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Sofeh street, Isfahan

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2

Recruitment center

Name of recruitment center

Shahidbeheshti Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooi Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nahid Moradi

Position

Student of medicine

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Behzad Barekatain

Position
Faculty member of Isfahan University of Medical Scienses

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Faculty member of Isfahan University of Medical Scienses

Latest degree
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Other areas of specialty/work
Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No Additional Informations

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
No Additional Informations

When the data will become available and for how long
No Additional Informations

To whom data/document is available
No Additional Informations

Under which criteria data/document could be used
No Additional Informations

From where data/document is obtainable
No Additional Informations

What processes are involved for a request to access data/document
No Additional Informations

Comments